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PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

FOR FURTHER ACTION

See paragraph 2 below

Applicant's or agent's file reference
see form PCT/ISA/220

International application No.
PCT/L2008/000786

International filing date (day/month/year)
11.06.2008

Priority date (day/month/year)
11.06.2007

International Patent Classification (IPC) or both national classification and IPC
INV. A61F2/00

Applicant
CONTIPI LTD.

1. This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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Date of completion of
this opinion

see form
PCT/ISA/210

Authorized Officer

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**WRITTEN OPINION OF THE
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Box No. I Basis of the opinion

1. With regard to the language, this opinion has been established on the basis of:
 the international application in the language in which it was filed
 a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 a sequence listing
 table(s) related to the sequence listing
 - b. format of material:
 on paper
 in electronic form
 - c. time of filing/furnishing:
 contained in the international application as filed.
 filed together with the international application in electronic form.
 furnished subsequently to this Authority for the purposes of search.
4. In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of

the entire international application

claims Nos. 29-52

because:

the said international application, or the said claims Nos. relate to the following subject matter which does not require an international search (*specify*):

the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

no international search report has been established for the whole application or for said claims Nos. 29-52

a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13ter.1(a) or (b).

a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

See Supplemental Box for further details

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**Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or
industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes: Claims	<u>3, 5-19</u>
	No: Claims	<u>1, 2, 4, 20-28</u>
Inventive step (IS)	Yes: Claims	<u>3, 5-7, 14-18</u>
	No: Claims	<u>1, 2, 4, 8-13, 19-28</u>
Industrial applicability (IA)	Yes: Claims	<u>1-28</u>
	No: Claims	

2. Citations and explanations

see separate sheet

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Re Item III.

Independent claims 29 and 52 refer to a method for ameliorating female incontinence which is a therapeutical method (Rule 39.1(iv) PCT during the search phase and Rule 67.1 (iv) PCT during the examination phase). In addition, as the device is inserted in the private sphere, it is excluded from industrial applicability, Articles 33(1), (4) PCT. Claims 30 - 51 being dependent on claim 29 equally do not fulfill the above requirements of the PCT.

Re Item V.

1 Reference is made to the following documents:

- D1: DE 198 16 349 A1 (HUEBNER FRANK-PETER [DE]) 14 October 1999 (1999-10-14)
- D2: WO 2005/087153 A (CONTIPI LTD [IL]; ZIV ELAN [IL]) 22 September 2005 (2005-09-22)
- D3: DE 271 657 C (LEVY) 17 March 1914 (1914-03-17)

2 INDEPENDENT CLAIM 1

- 2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.
Document D1 discloses (the references in parentheses applying to this document: col. 1, line 56 - col. 2, line 40, figures):

An apparatus for amelioration of urinary incontinence in a female subject (col. 1, lines 3-5), the apparatus comprising:
(a) a ring (2) with adjustable stiffness (see comment 1), adapted for intra-vaginal insertion; and
(b) a stabilizing projection (1), extending transversely to a plane of said stiffenable ring (2), said stabilizing projection having a size, shape, stiffness and position configured to

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stabilize said stiffenable ring within the vagina.

Comment 1:

The ring 2 is inflatably dependent on the use thereof, i.e. the stiffness of the ring can be adjusted to its needs, see column 2, lines 10 - 24 and especially the wording "Durch die **bedarfsgerecht** zunehmende Füllung des Ringpessars kann der Hebe- und Unterstützungseffekt des Silikonschalenpessars vergrössert werden...".

3 DEPENDENT CLAIMS 2, 4, 8 - 13, 19 - 28

3.1 Dependent claims 2, 4, 8-13, 20 - 28 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT), see documents D1 and D2 and their citations in the search report.

3.2 In claim 19 a slight constructional change in the design of the stabilizing extension of claim 1 is defined which comes within the scope of the customary practice followed by persons skilled in the art, especially as the advantages thus achieved can readily be foreseen. Consequently, the subject-matter of claim 19 also lacks an inventive step.

4 DEPENDENT CLAIMS 3, 5 - 7, 14 - 18

The combination of the features of dependent claims 3, 5-7, 13-20, 26 are neither known from, nor rendered obvious by, the available prior art. The reasons are as follows:

4.1 In document D1 a ring (2) is inflatable with gas or liquid. Said stiffenable ring is therefore adapted to switch from a first geometric configuration outside the body (the ring is not inflated) to a second configuration after intra vaginal insertion (the ring can be fully inflated) and as such D1 comprises all the technical features of claim 2.

Claim 3 being dependent on claim 2 claims that said switch from said first configuration to

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said second configuration is performed mechanically. This is not disclosed in D1 and as such claim 3 fulfills the requirement of novelty, Article 33(2) PCT.

The problem to be solved by a mechanical switch is to avoid any leakage problems that could arise with inflatable systems.

No other switch is suggested in D1 and although a mechanical switch is disclosed in document D3 (spring 8), both documents cannot be combined as their construction is completely different. Furthermore, due to the umbrella mechanism in D3, there are only two positions possible: closed and open and the opening diameter of the umbrella cannot be adjusted.

Therefore, the subject-matter of claim 1 involves an inventive step and meets the requirements of Article 33(3) PCT.

Claims 4 - 28 being dependent on claims 1 - 3 specify advantageous embodiments of the subject-matter of claims 1 - 3 and fulfill the requirements of Articles 33(2), (3) and (4) PCT as well.

4.2 Equally, **claim 5** being dependent on claims 1 and 4 fulfills the requirements of novelty and inventive step as briefly explained below:

Document D2 discloses (see page 16, line 4 - page 17, line 16; figures 10A - 11) an apparatus (1000) including a tensioning extension (1106) adapted to extend outside of the body, said tensioning extension (1106) adapted for selectively increasing and decreasing a rigidity of said ring after insertion thereof.

The tensioning extension of D2 solves the same problem as in D1, namely how to inflate the ring and is only an alternative to the pump inflation as disclosed in D1. As such claim 3 is not inventive in view of D1 and D2.

The subject-matter of claim 5 differs from this state of the art (D2) in that said apparatus

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includes a stiffening control.

In view of said difference the subject-matter of claims 4 and 5 is new and meets the requirements of Article 33(2) PCT.

The problem to be solved by a stiffening control is to suit the needs of individual conditions.

None of the prior art documents cited in the search report disclose any control mechanisms for intermediate steps to stiffen a ring.

Therefore, the subject-matter of claim 5 involves an inventive step and meets the requirements of Article 33(3) PCT.

Claims 5 - 28 being dependent on claims 1 and 4 specify advantageous embodiments of the subject-matter of claims 1 and 4 and fulfill the requirements of Articles 33(2), (3) and (4) PCT as well.

Possible steps after receipt of the international search report (ISR) and written opinion of the International Searching Authority (WO-ISA)

General information	For all international applications filed on or after 01/01/2004 the competent ISA will establish an ISR. It is accompanied by the WO-ISA. Unlike the former written opinion of the IPEA (Rule 66.2 PCT), the WO-ISA is not meant to be responded to, but to be taken into consideration for further procedural steps. This document explains about the possibilities.
Amending claims under Art. 19 PCT	Within 2 months after the date of mailing of the ISR and the WO-ISA the applicant may file amended claims under Art. 19 PCT directly with the International Bureau of WIPO. The PCT reform of 2004 did not change this procedure. For further information please see Rule 46 PCT as well as form PCT/ISA/220 and the corresponding Notes to form PCT/ISA/220.
Filing a demand for international preliminary examination	In principle, the WO-ISA will be considered as the written opinion of the IPEA. This should, in many cases, make it unnecessary to file a demand for international preliminary examination. If the applicant nevertheless wishes to file a demand this must be done before expiry of 3 months after the date of mailing of the ISR/ WO-ISA or 22 months after priority date, whichever expires later (Rule 54bis PCT). Amendments under Art. 34 PCT can be filed with the IPEA as before, normally at the same time as filing the demand (Rule 66.1 (b) PCT). If a demand for international preliminary examination is filed and no comments/amendments have been received the WO-ISA will be transformed by the IPEA into an IPRP (International Preliminary Report on Patentability) which would merely reflect the content of the WO-ISA. The demand can still be withdrawn (Art. 37 PCT).
Filing informal comments	After receipt of the ISR/WO-ISA the applicant may file informal comments on the WO-ISA directly with the International Bureau of WIPO. These will be communicated to the designated Offices together with the IPRP (International Preliminary Report on Patentability) at 30 months from the priority date. Please also refer to the next box.
End of the international phase	At the end of the international phase the International Bureau of WIPO will transform the WO-ISA or, if a demand was filed, the written opinion of the IPEA into the IPRP, which will then be transmitted together with possible informal comments to the designated Offices. The IPRP replaces the former IPER (international preliminary examination report).
Relevant PCT Rules and more information	Rule 43 PCT, Rule 43bis PCT, Rule 44 PCT, Rule 44bis PCT, PCT Newsletter 12/2003, OJ 11/2003, OJ 12/2003